

EXHIBIT 31

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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIOID LITIGATION

MDL No. 2804

Case No. 17-md-2804

CITY OF CLEVELAND OHIO and
THE STATE OF OHIO EX REL. ET AL

Judge Dan Aaron Polster

Plaintiffs,

v.

PURDUE PHARMA L.P., ET AL

Defendants.

AMENDED EXPERT REPORT OF SANDRA K.B. KINSEY, R.Ph, MBA.

audits of Giant Eagle pharmacies and HBC/GERx to test and approve sufficient controls are in place and effective. Giant Eagle and the DEA maintain a cooperative and engaging relationship and the DEA has never sanctioned Giant Eagle for failure to comply with any regulation or found them deficient in any controls.⁶⁷.

124. Summarizing the CSA, 21 CFR §1301.71, it states that, “All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” The statute continues with, “...the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion” and that, “Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant.”⁶⁸

B. Physical Security and Controls

125. 21 CFR §1301.72 details the physical security controls required for CII substances and CIII-CV. In accordance with the regulations, both HBC and GERx meet or exceed each of these requirements. For example:

- All controlled substances are housed in a steel cage or vault and no cross-docking allowed
- Security cameras, video surveillance and guards monitor the facilities
- For outbound product, inventory is counted before the business day starts, when it ends and prior to scheduled breaks
- For inbound product, inventory is counted at point of receipt and reserves slots verified

⁶⁷ Deposition of George Chunderlik, dated January 16, 2019, p. 266.

⁶⁸ 21 CFR §1301.71.

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- Limited personnel access to controlled substances, with a maximum of two employees at a single time for order fulfillment.
- Vocollect software application and hardware comprised of a headset and wearable scanner to communicate inventory location for accuracy of order fulfillment and replenishment
- Manhattan software application to manage incoming and outgoing orders, cycle counts, inventory reconciliation, audits, etc.
- Order specialists to monitor store orders for accuracy and appropriateness and any deviations from typical ordering patterns
- Beginning in 2013, daily threshold reports, redundant threshold systems and additional software applications for order monitoring.⁶⁹

126. Similarly, each individual Giant Eagle Pharmacy has security controls that meet or exceed each of the requirements of the Controlled Substances Act and those of the State of Ohio Board of Pharmacy through official written policies and procedures and unwritten standards of practice within the pharmacy industry. For example:

- Redundant surveillance and security systems covering the entire building and specific to the pharmacy
- Highly educated, licensed and trained pharmacists and pharmacy technicians
- Written policies and procedures, including Controlled Substance Dispensing Guidelines
- PMS for inventory management and automatic replenishment ordering
- Limited legal authority for review of all controlled substances orders

⁶⁹ Deposition of Walter Wayne Durr, dated January 22, 2019, at pp.83-91.

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- Inventory counts and back-counts with each prescription (CIIs) and monthly narcotic audit.
- CIIs kept isolated from other inventory in secured cabinet or locked safes with pharmacist-only access.⁷⁰

C. Overview of Giant Eagle's Inventory Management, Replenishment Pathway and Controls

127. During each step in the pathway of drug replenishment, Giant Eagle is hyper-focused on preventing theft and diversion. They have evolved business practices over the years as technology enables more automation for previously manual processes.

128. Giant Eagle pharmacies play an integral role in preventing theft and diversion by scrutinizing every controlled substance prescription that is presented by the patient. Giant Eagle authored and distributed Giant Eagle's Controlled Substance Dispensing Guidelines to be retained in all stores in addition to the DEA Pharmacist Manual.⁷¹ By confirming the legitimacy of the prescribed information, the pharmacist is ensuring that the product is not being dispensed inappropriately. After a prescription is filled in the PMS, inventory is automatically decremented to reflect current shelf stock. For CIIs, pharmacies manually count the inventory with each fill to ensure accurate on-hands and that on-hands match the inventory count in the PMS.

129. At the end of the day, the PMS will automatically generate a drug replenishment order based on the day's business and the need for product to fulfill future business. The pharmacist will review the controlled substances order for accuracy, electronically sign the order via legal authority and submit the order to the warehouse via CSOS.

⁷⁰ Deposition of George Chunderlik, dated January 16, 2019, pp. 263-264

⁷¹ Deposition of George Chunderlik, dated January 16, 2019, p. 252.

technology, training and executive leadership exclusively within Giant Eagle Pharmacy, HBC Service Company/GERx, and Giant Eagle's corporate office.

139. In order to fulfill the system obligations, the DEA has stated that distributors should engage in a "Know Your Customer" policy and take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and consequently, identify those transactions conducted by their customers that are suspicious in nature.⁷⁴ As noted by Plaintiff's expert, Seth B. Whitelaw, throughout his expert report, the concept of "Know Your Customer" is critical to a successful SOM system and that "knowing a pharmacy's product mix of controlled versus non-controlled prescriptions together with local data..." are important pieces of information for a customer profile.⁷⁵ In fact, the DEA makes, clear, the Know Your Customer requirement is the basis for determining whether a customer's purchases are to be considered legitimate or diversionary. Mr. Whitelaw goes on to admit, "However, it also is important to remember that knowing one's customer and making determinations of whether orders are suspicious or legitimate is not simply a scientific endeavor (e.g., just using thresholds and algorithms), but also is an art requiring training, experience, innate skepticism, and common sense."⁷⁶

140. Because Giant Eagle operates a captive self-distributor, it is intimately aware of its "Customer" as the "Customer" is its own stores. Giant Eagle's corporate leadership routinely visits stores, ensuring compliance to policies and procedures, rules and regulations. In addition, corporate buyers run daily reports to understand the pharmacy's product mix. They are keenly aware of the quantity of controlled versus non-controlled prescriptions and exactly how much

⁷⁴ Knowing Your Customer/Suspicious Orders Reporting. DEA Diversion Control Division, *available at* https://www.deadiversion.usdoj.gov/chem_prog/susp.htm (last accessed May 7, 2019).

⁷⁵ Expert Report of Dr. Seth B. Whitelaw, dated April 15, 2019, at 26:6.1.2.

⁷⁶ Expert Report of Dr. Seth B. Whitelaw, dated April 15, 2019, at 26:6.1.2.

product is flowing through the organization. In addition, Giant Eagle trusts the expertise of their pharmacists and pharmacy staff, appreciating their “training, experience, innate skepticism and common sense” that comes with the profession.

141. Giant Eagle has evolved their SOM system of integrated controls over the years as advancements were made in technology, physical infrastructures and general business practices. Although not required by law, in 2013, Giant Eagle initiated a monthly ordering threshold and daily reporting for controlled substances using nationwide averages to assist leadership in flagging orders that exceeded certain pre-determined parameters. The threshold system advanced to daily thresholds based on independent store dynamics.

142. The orders flagged by these reports do not definitively indicate a suspicious order, but rather, are used to identify certain stores and orders that need further investigation because the business exceeds that of other averages and norms by which the thresholds were established. Items which exceed the established threshold trigger are scrutinized and investigated by field level personnel to determine if the items need to be removed from the order and reported to the DEA.⁷⁷ Even after Giant Eagle implemented the threshold system, all flagged orders for controlled substances were cleared, validating that existing policies and procedures prevent theft and diversion.

143. Discovery shows that Giant Eagle’s integrated system of safety and controls is designed to largely prevent suspicious orders. Orders flagged by the threshold systems were all traced back to legitimate prescriptions and growth in the pharmacy business. Due to the overlapping checks and balances of the system to date, Giant Eagle has uncovered only two orders of concern that meet the DEA definition of “suspicious” and both orders were resolved

⁷⁷ HBC_MDL00132616.